THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant(s):	Petermann, et al.
Appl. No.:	10/539,092
Conf. No.:	9222
Filed:	June 15, 2005
Title:	CHEMICALLY ACIDIFIED FORMULA
Art Unit:	1794
Examiner:	Dees, Nikki H.
Docket No.:	0112701-00626

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' REPLY BRIEF

Sir:

I. INTRODUCTION

Appellants submit Appellants' Reply Brief in response to the Examiner's Answer dated August 20, 2009 pursuant to 37 C.F.R. § 41.41(a). Appellants respectfully submit that the Examiner's Answer has failed to remedy the deficiencies with respect to the Final Office Action dated April 2, 2009 as noted in Appellants' Appeal Brief filed on June 15, 2009, for at least the reasons set forth below. Accordingly, Appellants respectfully request that the rejections of pending Claims 1-2, 5-11 and 13 be reversed.

II. THE REJECTION OF CLAIMS 1-2, 5-11 AND 13 UNDER 35 U.S.C. § 103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS NOT ESTABLISHED A PRIMA FACIE CASE OF OBVIOUSNESS WITH RESPECT TO THE CITED REFERENCES

Appellants respectfully request that the Board reverse the rejections of Claims 1-2, 5-11 and 13 under 35 U.S.C. §103(a) because the Examiner has still failed to establish a *prima facie* case of obviousness with respect to the cited references. Appellants respectfully submit that the cited references fail to disclose or suggest each and every element of the present claims and that the skilled artisan would have no reason to combine *DeWille* and *PURAC* to arrive at the present claims.

A. *DeWille* and *PURAC* fail to disclose or suggest each and every element of the present claims

In the Examiner's Answer, the Examiner asserts that "[o]ne of ordinary skill would have recognized that the teaching of the addition of food grade acid [in *DeWille*] to a foodstuff is 'direct acidification' of the foodstuff." See, Examiner's Answer, page 10, lines 9-16. However, Appellants disagree and submit that *DeWille* fails to even use the phrase "L(+)-lactic acid" at any place in the disclosure. The Examiner agrees. See, Final Office Action, paragraph 8. Indeed, *DeWille* fails to even mention any of the enantiomers of lactic acid at any place in the disclosure. Accordingly, the Examiner also fails to point to any disclosure of same in *DeWille*. Further, because *PURAC* is simply a catalogue listing natural lactic acid and lactate forms, *PURAC* also fails to disclose or suggest any direct acidification of a foodstuff with L(+)-lactic acid.

In response to Appellants' arguments that *DeWille* and *PURAC* also fail to disclose or suggest nutritional infant formulas wherein at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid, the Examiner asserts that the skilled artisan "would have been able to modify the nutritional profile of *DeWille* et al. in order to provide a nutritional formula that met the nutritional needs of infants." See, Examiner's Answer, page 10, line 17-page 11, line 6. However, Appellants disagree. As discussed above, *DeWille* fails to even mention any of the enantiomers of lactic acid at any place in the disclosure, let alone specific amounts of L(+)-

lactic acid that may be used for infant formulas. Appellants respectfully submit that it would not have been obvious to modify an infant formula in such a manner when the cited art fails to even disclose the use of L(+)-lactic acid in foodstuffs, let alone in specific amounts that must also provide sufficient caloric intake and the proper proportion of fat, protein and carbohydrates for an infant yet be well-tolerated by the infant at the same time.

The Examiner further asserts that Appellants have argued the cited references individually and that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See, Examiner's Answer, page 11, lines 7-12. However, Appellants respectfully submit that, to the extent that the references are discussed individually, it is not to address the rejections as anticipation rejections, but rather to point out the deficiencies of the cited references. In this case, not only do the cited references fail to disclose or suggest each and every element of the present claims, the skilled artisan would not have any reason to combine the cited references to arrive at the present claims.

B. Contrary to the Examiner's assertion, the skilled artisan would have no reason to combine the cited references to arrive at the present claims.

The Examiner asserts that "[t]he selection of L(+) lactic acid for addition to foodstuffs where lactic acid is specifically tough as an acidulent in the nutritional formula of *DeWille* et al. would have been obvious to one of ordinary skill in the art" and that Appellants are "doing no more than using a known compound for its intended use in order to provide the predictable result of acidifying a foodstuff." See, Examiner's Answer, page 11, lines 13-19. Appellants disagree. Simply citing a product data sheet (*PURAC*) that publishes information for two of many different kinds "lactic acid" in no way remedies the deficiency of *DeWille* and provides no specific guidance to use L(+)-lactic acid to directly acidify a nutritional infant formula in accordance with the present claims. Simply disclosing analytical information regarding two lactic acid ingredients does not provide one skilled in the art any reason to use the specific lactic acid disclosed in *PURAC* as the general lactic acid taught in *DeWille* in the absence of hindsight.

Indeed, nothing in *PURAC* teaches or suggests that the lactic acid taught therein is desirable or safe for use in infant formulations in accordance with the present claims. As a result, the skilled artisan would have no reason to specifically choose L(+)-lactic acid from

PURAC to add to the nutritional formulation of *DeWille*. Nevertheless, even *DeWille* is not concerned with infant formulas as it teaches components that would not be acceptable in an infant formula such as the stabilizing system comprising high methoxy pectin, which is an essential feature of *DeWille*.

The Examiner also asserts that "any judgment of obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning" but that "so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." See, Examiner's Answer, page 11, line 20-page 12, line 4. However, Appellants respectfully submit that for a combination of references to be proper under 35 U.S.C. §103(a), the claimed elements must be disclosed by the combination of references and the skilled artisan must have had a reason to combine the two references. Appellants submit this is not the case with the present claims.

For example, in contrast to the Examiner's assertion that "[t]he availability of L(+)-lactic acid for addition to foodstuffs was known in the art at the time Appellant's invention was made," see, Examiner's Answer, page 12, lines 5-6, Appellants submit that the Examiner still fails to point to any disclosure in either *DeWille* or *PURAC*, where it is shown to add L(+)-lactic acid to foodstuffs. Further, because *PURAC* is simply a catalogue listing that publishes information for two of the many different kinds of "lactic acid," the skilled artisan would have no reason to look to a catalogue listing to modify *DeWille*. Accordingly, the skilled artisan would not have found it necessary to replace the lactic acid of *DeWille* with L(+)-lactic acid. Thus, the skilled artisan would not have any reason to combine *DeWille* with *PURAC* absent any hindsight reconstruction.

Indeed, the Examiner assumes that it would have been within the ordinary skill of the artisan at the time the claimed invention was made because the references relied upon allegedly teach that all aspects of the claimed invention were individually known in the art. However, this conclusory statement is not sufficient to establish a *prima facie* case of obviousness without some objective reason to utilize the teachings of the references to arrive at the invention. *Ex parte Levengood*, 28 USPQ 2d 1300 (Bd. Pat. App. & Inter. 1993). There must be some articulated reasoning with some rational underpinning to support the legal conclusion of

obviousness by the Examiner. *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

III. THE REJECTION OF CLAIMS 1 AND 5-6 UNDER 35 U.S.C. § 103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS NOT ESTABLISHED A PRIMA FACIE CASE OF OBVIOUSNESS WITH RESPECT TO THE CITED REFERENCES

Appellants respectfully request that the Board reverse the rejections of Claims 1 and 5-6 under 35 U.S.C. §103(a) because the Examiner has still failed to establish a *prima facie* case of obviousness with respect to the cited references. Appellants respectfully submit that the cited references fail to disclose or suggest each and every element of the present claims and that the skilled artisan would have no reason to combine *Schwartz* and *WHO* to arrive at the present claims.

A. *Schwartz* and *WHO* fail to disclose or suggest each and every element of the present claims

Initially, the Examiner asserts that "*Wong* is not used as prior art for the rejection, and therefore should not be regarded as deficient." See, Examiner's Answer, page 13, lines 18-20. Thus, the Examiner admits that *Wong* is not used substantively in the rejection.

In the Examiner's Answer, the Examiner continues to assert that *Schwartz* clearly teaches the addition of lactic acids to foodstuffs to be administered to infants and "*WHO* specifically teaches that D(-) and DL-lactic acid are not suitable for inclusion in foodstuffs to be administered to infants." See, Examiner's Answer, page 13, lines 8-12. However, Appellants disagree. Instead, the Examiner admits the that *Schwartz* fails to disclose or suggest L(+)-lactic acid. See, Examiner's Answer, page 12, lines 17-19. Further, *WHO* fails to remedy the deficiency of *Schwartz* with regard to an L(+)-lactic acid because *WHO* fails to disclose or suggest directly acidifying an infant formula using L(+)-lactic acid. Indeed, the Examiner merely asserts that *WHO* discloses that D(-) and DL-lactic acid are not suitable for inclusion in

foodstuffs to be administered to infants. This is not equivalent to a disclosure of L(+)-lactic acid to infants.

The Examiner asserts that, in view of *WHO*, one of ordinary skill would have recognized that L-(+) lactic acid is the obvious choice for inclusion in infant formula of *Schwartz* because *WHO* teaches away from DL lactic acid and D(-) lactic acid administration to infants and, therefore, the only remaining choice for lactic acid that one would administer to infants would be L(+) lactic acid. See, Examiner's Answer, page 13, lines 1-3.

Appellants respectfully disagree and submit that *WHO* mentions that infants had more difficulty metabolizing D(-) lactic acids than L(+) lactic acids based on urinary excretion. Although D(-) lactic acid may have been harder to metabolize than L(+)-lactic acid, no part of *WHO* teaches that infants can positively utilize L(+)-lactic acid alone or that L(+)-lactic acid should be favorably administered to infants. There is no evidence that *WHO* was referring specifically to D(-) lactic acid avoidance rather than L(+) lactic acid avoidance. Rather, *WHO* discloses that the urinary excretion of either form of lactic acid indicates that a young infant cannot utilize lactic acid at a rate which can keep up with 0.35% in the diet. See, *WHO*, page 4, lines 16-19. As a result, based on the negative results of the racemic DL lactic acid as a whole, *WHO* actually teaches away from using any type of lactic acid (whether in L(+) and D(-) lactic acid forms) in nutritional infant formulas.

B. Contrary to the Examiner's assertion, the skilled artisan would have no reason to combine the cited references to arrive at the present claims.

The Examiner asserts that because *Schwartz* allegedly discloses the addition of lactic acids to foodstuffs to be administered to infants and because *WHO* teaches that D(-) and DL-lactic acid are not suitable for inclusion in foodstuffs to be administered to infants, one of ordinary skill would have recognized that only L(+)-lactic acid was suitable for addition to infant foodstuffs. See, Examiner's Answer, page 13, lines 8-14. However, Appellants disagree.

As discussed above, *Schwartz* fails to specifically teach or suggest using L(+)-lactic acid to directly acidify the infant milk. The Examiner admits same. See, Examiner's Answer, page 12, lines 17-19. Further, Appellants respectfully submit that *WHO* teaches away from general DL lactic acid usage as a whole in nutritional infant formulas. As discussed above, in *WHO*,

DL-lactic acid, a racemic mixture of L(+) and D(-) lactic acid forms, was administered to infants. Neither L(+) nor D(-) lactic acid forms were individually administered. *WHO* mentions that infants had more difficulty metabolizing D(-) lactic acids than L(+) lactic acids based on urinary excretion. Although D(-) lactic acid may have been harder to metabolize than L(+)-lactic acid, no part of *WHO* teaches that infants can positively utilize L(+)-lactic acid alone or that L(+)-lactic acid should be favorably administered to infants. There is no evidence that *WHO* was referring specifically to D(-) lactic acid avoidance rather than L(+) lactic acid avoidance. Rather, *WHO* discloses that the urinary excretion of either form of lactic acid indicates that a young infant cannot utilize lactic acid at a rate which can keep up with 0.35% in the diet. See, *WHO*, page 4, lines 16-19. As a result, based on the negative results of the racemic DL lactic acid as a whole, *WHO* actually teaches away from using any type of lactic acid (whether in L(+) and D(-) lactic acid forms) in nutritional infant formulas.

The Examiner also asserts that "there is no hindsight reconstruction required, as all of the elements of Appellant's invention were known in the art at the time the invention was made to have been used for the same purpose which appellant is claiming." See, Examiner's Answer, page 13, lines 15-17. However, Appellants respectfully disagree and submit that *Schwartz* admittedly fails to disclose L(+)-lactic acid. Further, Appellants respectfully submit that the Examiner mischaracterizes the disclosure of *WHO*, as is discussed above. Thus, the skilled artisan would not have any reason to combine *Schwartz* with *WHO* absent any hindsight reconstruction.

IV. THE REJECTION OF CLAIMS 1 AND 5-11 UNDER 35 U.S.C. § 103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS NOT ESTABLISHED A PRIMA FACIE CASE OF OBVIOUSNESS WITH RESPECT TO THE CITED REFERENCES

Appellants respectfully request that the Board reverse the rejections of Claims 1 and 5-11 under 35 U.S.C. §103(a) because the Examiner has still failed to establish a *prima facie* case of obviousness with respect to the cited references. Appellants respectfully submit that the cited references fail to disclose or suggest each and every element of the present claims and that the

skilled artisan would have no reason to combine *Schwartz* and *PURAC* to arrive at the present claims.

A. *Schwartz* and *PURAC* fail to disclose or suggest each and every element of the present claims

In the Examiner's Answer, the Examiner continues to assert that "*Schwartz* teaches the addition of lactic acid to milk to be fed to infants" and "*PURAC* teaches a foodgrade L(+)-lactic acid." Regardless, *Schwartz* and *PURAC* fail to disclose or suggest a nutritional infant formula directly acidified by L(+)-lactic acid, a nutritional infant formula wherein at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid, or suggest directly acidifying the nutritional formula by using a lactic acid chosen from the group consisting of isolated and purified L(+)-lactic acid. The Examiner does not specifically refute Appellants assertion that *Schwartz* and *PURAC* fail to disclose same. Accordingly, in contrast to the Examiner's assertion that "[t]he combination of prior art . . . provide[s] for all of the limitations of Appellants claims," Appellants respectfully submit that the cited references are deficient with respect to the present claims.

B. Contrary to the Examiner's assertion, the skilled artisan would have no reason to combine the cited references to arrive at the present claims.

The Examiner asserts that because *Schwartz* allegedly discloses the addition of lactic acids to foodstuffs to be administered to infants and because *PURAC* teaches a food grade L(+)-lactic acid, one of ordinary skill in the art at the time the invention was made wishing to provide lactic acid for use in infant foodstuffs would have found it obvious to utilize a food grade lactic acid as taught by *PURAC* to do so. See, Examiner's Answer, page 14, lines 12-15. However, Appellants disagree.

As discussed above, *Schwartz* fails to specifically teach or suggest using L(+)-lactic acid to directly acidify the infant milk. The Examiner admits same. See, Examiner's Answer, page 12, lines 17-19. Further, Appellants respectfully submit that *PURAC* fails to disclose, suggest or even mention application of its product to infant formulas. In addition, simply citing a product

data sheet (*PURAC*) that publishes information for two of many different kinds "lactic acid" in no way remedies the deficiency of *Schwartz* and provides no specific guidance to use L(+)-lactic acid to directly acidify a nutritional infant formula in accordance with the present claims. Just disclosing analytical information regarding two lactic acid ingredients does not provide one skilled in the art any reason to use the specific lactic acid disclosed in *PURAC* as the general lactic acid taught in *Schwartz* in the absence of hindsight.

The Examiner also asserts that "any judgment of obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning" but that "so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." See, Examiner's Answer, page 15, lines 1-6. However, Appellants respectfully submit that for a combination of references to be proper under 35 U.S.C. §103(a), the claimed elements must be disclosed by the combination of references and the skilled artisan must have had a reason to combine the two references. Appellants submit this is not the case with the present claims.

For example, in contrast to the Examiner's assertion that "[t]he availability of L(+)-lactic acid for addition to foodstuffs was known in the art at the time Appellant's invention was made," see, Examiner's Answer, page 15, lines 7-10, Appellants submit that the Examiner still fails to point to any disclosure in either *Schwartz* or *PURAC*, where it is shown to add L(+)-lactic acid to foodstuffs. Further, because *PURAC* is simply a catalogue listing that publishes information for two of the many different kinds of "lactic acid," the skilled artisan would have no reason to look to a catalogue listing to modify *Schwartz*. Accordingly, the skilled artisan would not have found it necessary to replace the lactic acid of *Schwartz* with L(+)-lactic acid. Thus, the skilled artisan would not have any reason to combine *Schwartz* with *PURAC* absent any hindsight reconstruction.

V. THE REJECTION OF CLAIMS 1 AND 5-11 UNDER 35 U.S.C. § 103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS NOT ESTABLISHED A PRIMA FACIE CASE OF OBVIOUSNESS WITH RESPECT TO THE CITED REFERENCES

Appellants respectfully request that the Board reverse the rejections of Claims 1 and 5-11 under 35 U.S.C. §103(a) because the Examiner has still failed to establish a *prima facie* case of obviousness with respect to the cited references. Appellants respectfully submit that the cited references fail to disclose or suggest each and every element of the present claims and that the skilled artisan would have no reason to combine *Takahara* and *WHO* to arrive at the present claims.

A. *Takahara* and *WHO* fail to disclose or suggest each and every element of the present claims

In the Examiner's Answer, the Examiner continues to assert that "*Takahara* teaches an acidified whole milk beverage comprising whole milk and an organic acid," which allegedly includes lactic acid. The Examiner also asserts that *WHO* specifically teaches that D(-) and DL-lactic acid are not suitable for inclusion in foodstuffs to be administered to infants." See, Examiner's Answer, page 15, line 18-page 16, line 6. However, Appellants disagree. Instead, *Takahara* is generally directed to an acidified whole milk beverage that uses an acidifying agent such as fruit juice or organic acid. Nevertheless, *Takahara* fails to disclose or suggest any use of L(+)-lactic acid as required by the present claims. The Examiner admits the same. See, Final Office Action, paragraph 31. Further, *WHO* fails to remedy the deficiencies of *Takahara* with regard to an L(+)-lactic acid because *WHO* fails to disclose or suggest directly acidifying an infant formula using L(+)-lactic acid. Indeed, the Examiner merely asserts that *WHO* discloses that D(-) and DL-lactic acid are not suitable for inclusion in foodstuffs to be administered to infants. This is not equivalent to a disclosure of L(+)-lactic acid to infants.

The Examiner asserts that, in view of *WHO*, one of ordinary skill would have recognized that L-(+) lactic acid is the obvious choice for inclusion in infant formula of *Takahara* because *WHO* teaches away from the use of DL lactic acid and D(-) lactic acid in foodstuffs to be administered to infants and that only L(+) lactic acid would be suitable for addition to infant foods. See, Examiner's Answer, page 16, lines 11-17.

Appellants respectfully disagree and submit that *WHO* mentions that infants had more difficulty metabolizing D(-) lactic acids than L(+) lactic acids based on urinary excretion.

Although D(-) lactic acid may have been harder to metabolize than L(+)-lactic acid, no part of *WHO* teaches that infants can positively utilize L(+)-lactic acid alone or that L(+)-lactic acid should be favorably administered to infants. There is no evidence that *WHO* was referring specifically to D(-) lactic acid avoidance rather than L(+) lactic acid avoidance. Rather, *WHO* discloses that the urinary excretion of either form of lactic acid indicates that a young infant cannot utilize lactic acid at a rate which can keep up with 0.35% in the diet. See, *WHO*, page 4, lines 16-19. As a result, based on the negative results of the racemic DL lactic acid as a whole, *WHO* actually teaches away from using any type of lactic acid (whether in L(+) and D(-) lactic acid forms) in nutritional infant formulas.

B. Contrary to the Examiner's assertion, the skilled artisan would have no reason to combine the cited references to arrive at the present claims.

The Examiner asserts that because *Takahara* teaches an acidified whole milk beverage comprising whole milk and an organic acid, which allegedly includes lactic acid, and because WHO teaches that D(-) and DL-lactic acid are not suitable for inclusion in foodstuffs to be administered to infants, one of ordinary skill would have recognized that only L(+)-lactic acid was suitable for addition to infant foodstuffs. See, Examiner's Answer, page 16, lines 11-17. However, Appellants disagree.

As discussed above, *Takahara* fails to disclose or suggest any use of L(+)-lactic acid as required by the present claims. Further, Appellants respectfully submit that *WHO* teaches away from general DL lactic acid usage as a whole in nutritional infant formulas. As discussed above, in *WHO*, DL-lactic acid, a racemic mixture of L(+) and D(-) lactic acid forms, was administered to infants. Neither L(+) nor D(-) lactic acid forms were individually administered. *WHO* mentions that infants had more difficulty metabolizing D(-) lactic acids than L(+) lactic acids based on urinary excretion. Although D(-) lactic acid may have been harder to metabolize than L(+)-lactic acid, no part of *WHO* teaches that infants can positively utilize L(+)-lactic acid alone or that L(+)-lactic acid should be favorably administered to infants. There is no evidence that *WHO* was referring specifically to D(-) lactic acid avoidance rather than L(+) lactic acid avoidance. Rather, *WHO* discloses that the urinary excretion of either form of lactic acid indicates that a young infant cannot utilize lactic acid at a rate which can keep up with 0.35% in

the diet. See, *WHO*, page 4, lines 16-19. As a result, based on the negative results of the racemic DL lactic acid as a whole, *WHO* actually teaches away from using any type of lactic acid (whether in L(+) and D(-) lactic acid forms) in nutritional infant formulas.

The Examiner also asserts that "there is no hindsight reconstruction required, as all of the elements of Appellant's invention were known in the art at the time the invention was made to have been used for the same purpose which appellant is claiming." See, Examiner's Answer, page 13, lines 15-17. However, Appellants respectfully disagree and submit that *Takahara* admittedly fails to disclose L(+)-lactic acid. Further, Appellants respectfully submit that the Examiner mischaracterizes the disclosure of *WHO*, as is discussed above. Thus, the skilled artisan would not have any reason to combine *Takahara* with *WHO* absent any hindsight reconstruction.

VI. CONCLUSION

For the foregoing reasons, Appellants respectfully submit that the Examiner's Answer does not remedy the deficiencies noted in Appellants' Appeal Brief with respect to the Final Office Action. Therefore, Appellants respectfully request that the Board of Appeals reverse the obviousness rejections with respect to Claims 1-2, 5-11 and 13.

No fee is due in connection with this Reply Brief. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 0112701-00626 on the account statement.

Respectfully submitted,

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